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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,498	03/12/2001	John Christopher Barron	BSC-162	1361
21323	7590	12/04/2003	EXAMINER	
TESTA, HURWITZ & THIBEAULT, LLP			DAVIS, DANIEL J	
HIGH STREET TOWER			ART UNIT	PAPER NUMBER
125 HIGH STREET			3731	
BOSTON, MA 02110			DATE MAILED: 12/04/2003	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/804,498	BARRON ET AL.
	Examiner	Art Unit
	D. Jacob Davis	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 September 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 11-22 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 4) Interview Summary (PTO-413) Paper No(s). _____.
5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Drawings

The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81. No new matter may be introduced in the required drawing.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. “A protective cover *formed from* a solid, non-hollow, non-inflatable mass...” Firstly, neither “non-hollow” nor “non-inflatable” is supported in the original disclosure. Secondly, the limitation is interpreted as a product-by-process limitation, which the disclosure also fails to support.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Gellman (WO 99/37216). In Fig. 43, Gellman discloses a medical device comprising a bone anchor 888 and a protective cover 890. The cover is bioabsorbable (page 37, lines 17-22). Page 29, lines 25--et seq. disclose bioabsorbable materials.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Birk et al. (US 5,961,528). Birk discloses a medical device in Fig. 3 comprising a bone anchor 46 and a cover 44. The cover 44 is made of metal (Col. 5, lines 11--et seq.). Metal is a substantially deformable material.

Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Iverson et al. (US 6,045,553). Regarding claims 1 and 3, Iverson discloses a medical device 14 comprising a "bone anchor" with a ceramic coating. The coating is regarded

as the protective cover. The ceramic cover is “substantially brittle,” which, considering the small thickness of the coating, could be easily broken.

Claims 1, 2, 4-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Draenert (US 5,048,050). Draenert discloses in Figure 1 a protective cover 10 for a bone anchor (Col. 3, lines 11-16). Since the protective cover may be made of a bioabsorbable collagen (Col. 4, lines 55-59), it is inherently deformable. An antibiotic may be added to the material of the protective cover 10 (Col. 5, lines 36-41).

Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Schenk (US 5,997,541). Shenk discloses a protective cover 1 that is bioabsorbable and that may be made of many of the same claimed materials, such as polyglycolide (Col. 4, lines 37-59). Other possible materials include glasses and ceramics (Col. 4, lines 60-64), which inherently are brittle.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being obvious over Gellman et al. in view of Gittos et al. (US 3,758,690). Gellman discloses that the cover is made of a gelatin. The patent further describes the gelatin as "similar to a pill capsule" (page 3, lines 21-22). Gittos teaches a "hard or soft gelatin capsule" pill for "oral administration" (Col. 5, lines 5-8 and 25-32). The described soft gelatin capsule is "substantially deformable." Both capsules would be as thin as possible for easy digestion. Because of the thin shell and the inherent brittle nature of hardened gelatin, the hard form of the gelatin capsule is "substantially brittle."

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being obvious over Gellman et al. The patent fails to disclose in the embodiment of Fig. 43 the use of an antibiotic disposed within the gelatin material. Nevertheless, page 3, lines 23-25 teach that an antibiotic may be incorporated within the cover to prevent infection. Page 3, lines 26-30 teach the various types of antibiotics. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to dispose an antibiotic within the cover to prevent infection.

Responses to Arguments

Applicants filed arguments along with an amendment on September 17, 2003.

The added limitation, "*formed from* a solid, non-hollow, non-inflatable mass..." is considered a product-by-process limitation. It is not required that the references actually disclose how the device was made, or what it was made from. The covers of the various applications may be "formed from" such a mass and thus they meet the limitation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

DJD
November 26, 2003


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700